

**UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY**

**IN RE: VALSARTAN LOSARTAN,
AND IRBESARTAN PRODUCTS
LIABILITY LITIGATION**

MDL No. 2875

**Honorable Renée Marie Bumb,
District Judge**

This Document Relates to All Actions

**DEFENDANT ZHP'S RESPONSE TO PLAINTIFFS' PROPOSED
FINDINGS OF FACT IN ACCORDANCE WITH SPECIAL MASTER
ORDER NO. 98**

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Defendant Zhejiang Huahai Pharmaceutical Co., Ltd. (“ZHP”) hereby submits its responses to Plaintiffs’ proposed findings of fact in accordance with Special Master Order No. 98 (“SMO 98”).

As a preliminary matter, ZHP generally objects to Special Master Order No. 98 on the merits and reserves all rights to challenge the order in full. The Special Master has, however, ordered ZHP to respond to an “adverse inference” instruction proposed by Plaintiffs. ZHP objects to Plaintiffs’ submission because: (1) it goes beyond the sanctions authorized by the Special Master; and (2) the specific findings of fact proposed are contrary to the facts in the record in this litigation.

I. PLAINTIFFS’ PROPOSED FINDINGS OF FACT ARE NOT AUTHORIZED BY THE SPECIAL MASTER’S ORDER.

As explained in ZHP’s forthcoming Objections to SMO No. 98, no adverse inference is appropriate in this case. Moreover, the instructions proposed by Plaintiffs are inherently improper because they go far beyond allowing the jury to make an “adverse inference” regarding the content of the allegedly missing discovery, and instead direct the jury to find in favor of Plaintiffs on the substantive merits of their claims.

As courts have recognized, the language of an adverse inference instruction is “delineated [by] three levels . . . differing in severity based on the nature of the spoliating party’s conduct.” *United States v. Suarez*, No. 09-932, 2010 WL 4226524, at *9 (D.N.J. Oct. 21, 2010) (citing *Pension Comm. v. Banc of Am. Sec.*,

LLC, 685 F. Supp. 2d 456 (S.D.N.Y. 2010) (*abrogated in non-relevant part by Chin v. Port Auth. of N.Y. & N.J.*, 685 F.3d 135, 162 (2d Cir. 2012)). “In its most harsh form . . . a jury can be instructed that certain facts are deemed admitted and must be accepted as true.” *Id.* at *10. In addition, when a party has acted “willfully or recklessly” in its discovery obligations, “a court may impose a mandatory presumption,” though “[e]ven a mandatory presumption . . . is considered to be rebuttable.” *Id.* Finally, “[t]he least harsh instruction permits (but does not require) a jury to presume that the lost evidence is both relevant and favorable to the innocent party. If it makes this presumption, the spoliating party’s rebuttal evidence must then be considered by the jury, which must then decide whether to draw an adverse inference against the spoliating party.” *Id.*

Here, the Special Master expressly recognized that ZHP’s alleged discovery conduct does not justify the extreme sanctions of deeming Plaintiffs’ allegations “admitted” or precluding “ZHP and its subsidiaries . . . from defending Plaintiffs’ claims.” (ECF [2712](#) at 1.) To the contrary, the Special Master repeatedly stated that the evidence in the record favored the imposition of “lesser sanctions.” (*Id.* at 33-36.) In authorizing an “adverse inference instruction,” the Special Master instead agreed to an instruction allowing the jury to conclude that the information that “Mr. Chen’s deposition and the requested documents would have provided would be adverse to ZHP.” (*Id.* at 36.)

Plaintiffs' proposed instructions, by contrast, direct the jury to find in Plaintiffs' favor on the key elements of their claims. Specifically, Plaintiffs propose instructing the jury that the "Court has made" various "findings of fact with regard to ZHP that you are required to accept as true in evaluating the evidence and reaching your verdict." (ECF [2721-1](#) at 1.) Notably, the facts that Plaintiffs would have the jury "accept as true," with no ability on the part of ZHP to offer rebuttal evidence, go to some of the most hotly-contested issues in the litigation, including whether ZHP was aware of the presence of nitrosamines in valsartan API prior to 2018 and whether ZHP actively took steps to conceal that information. As a result, Plaintiffs' proposal is akin to a directed verdict in favor of Plaintiffs on the substantive merits of Plaintiffs' claims. *See Connecticut v. Johnson*, 460 U.S. 73, 84 (1983) ("[A] conclusive presumption . . . is the functional equivalent of a directed verdict on that issue.").

For this reason alone, Plaintiffs' proposed "findings of fact" should be rejected.

II. PLAINTIFFS' PROPOSED FINDINGS OF FACT ARE INCONSISTENT WITH THE FACTS IN THE RECORD.

In addition, all of Plaintiffs' proposed "findings of fact" are either unnecessary because they are already established by evidence in the record or are improper because they are contrary to the evidence. As a result, ZHP objects to each of Plaintiffs' proposed findings, as set forth more fully below:

PROPOSED FINDING OF FACT 1: Baohua Chen is the CEO and the highest-level executive in ZHP. (SMO 98, at 1-2).

RESPONSE: ZHP objects to this instruction because the information at issue is available from the evidence produced during discovery and therefore does not require or warrant a factual finding by the Court based on the alleged unavailability of evidence. (*See, e.g.*, Dep. of Jucai Ge 364:5-9, Apr. 30, 2021 (ECF [1900-5](#)) (“Mr. Chen has been either the general manager or the chairman of the board since I joined the company. That position is the highest position in the companies. You know, our ZHP has many companies or subsidiaries.”).) Moreover, Mr. Chen’s title is not “CEO” but “President.” (*See* Dep. of Jie Wang 151:19-24, May 18, 2021 (ECF [2569-5](#) at Ex. 117) (clarifying that Mr. Chen’s title was “president” and not “CEO” of ZHP).)

PROPOSED FINDING OF FACT 2: Baohua Chen had direct involvement with issues central to this case. (SMO 98, at 3).

RESPONSE: ZHP objects to this instruction because, to the extent there is any truth to it, that evidence is already available in the record. Specifically, there is available evidence demonstrating that Mr. Chen had involvement in the company’s response to the discovery of NDMA in ZHP’s valsartan API in 2018. (*See* Dep. of Min Li, Ph.D. 581:9-582:5, Apr. 22, 2021 (ECF [2663-12](#)) (describing Mr. Chen’s general involvement following the discovery of NDMA in valsartan).) But the

proposed instruction is factually incorrect—and directly contradicted by the record—to the extent it suggests that Mr. Chen played an active role in the development of the manufacturing process for valsartan, which is the key issue in the case. Indeed, witnesses have repeatedly testified that Mr. Chen would not have knowledge of science issues related to the development or manufacture of valsartan API prior to the recall. (*See, e.g.*, Dep. of Jucai Ge 364:22-365:8, Apr. 30, 2021 (ECF [1900-5](#)) (testifying that Mr. Chen “never was involved in specific product development or the drafting of documents like the deviation investigation or process control”); *id.* 364:9-14 (“Mr. Chen’s role is to formulate strategies and manage vice presidents. I don’t think he is involved in the day-to-day activities of the API of finished dose product manufacturing. Simply put, I don’t think he has any time for that.”).)

PROPOSED FINDING OF FACT 3: Baohua Chen’s involvement and authority with respect to the development, manufacture, sale, and recall of ZHP’s Valsartan was substantial, and it is likely that Mr. Chen has personal, unique firsthand knowledge regarding the matters at issue in this case. (SMO 98, at 3).

RESPONSE: ZHP objects to this instruction because it is false and contrary to the evidence in the record, as explained above. The evidence in the record establishes that Mr. Chen did not have any firsthand knowledge related to the scientific development, manufacture or sale of valsartan API, much less “unique” knowledge

not held by anyone else at the company. (*See, e.g.*, Dep. of Jucai Ge 364:5-14, Apr. 30, 2021 (ECF [1900-5](#)) (“I don’t think [Mr. Chen] is involved in the day-to-day activities of the API or finished dose product manufacturing. Simply put, I don’t think he has any time for that.”); *id.* 368:2-5 (“For the NDMA impurity investigation [in 2018], Mr. Chen never got involved in the root cause analysis, root cause investigation or creation of the deviation report. He never got involved.”).)

PROPOSED FINDING OF FACT 4: During the course of discovery in this case, when the Parties were required to produce documents and conduct the depositions of witnesses, the Court ordered ZHP to produce Baohua Chen for his deposition by the Plaintiffs. ZHP violated the Court Order requiring ZHP to produce Mr. Chen for his deposition, and Mr. Chen was not produced for his deposition. This deprived the Plaintiffs of their right to take the deposition of Mr. Chen. (SMO 98, at 2-4, 10-13, 19-21, 25-26, 30, 32).

RESPONSE: ZHP objects to this instruction because it misrepresents the facts relevant to the inability of ZHP to produce Mr. Chen, a Chinese citizen and resident, for deposition. To the extent any instruction regarding ZHP’s discovery conduct is appropriate, it should be revised as follows: “During the course of discovery in this case, when the Parties were required to produce documents and conduct the depositions of witnesses, the Court ordered ZHP to produce Baohua

Chen for his deposition by the Plaintiffs. Despite ZHP's efforts to obtain permission from the government of China for Mr. Chen to travel outside of mainland China to provide deposition testimony, the government of China refused. As a result, ZHP was unable to produce Mr. Chen for his deposition and Mr. Chen was unable to testify."

PROPOSED FINDING OF FACT 5: During the course of discovery in this case, ZHP was also required by Court Orders to produce relevant documents, and failed to fully comply with those Court Orders. In addition to the failure to produce certain documents at all, documents that were produced were not produced in the required form. For example, ZHP was required by Court Orders to produce the July 27, 2017 email written by Jinsheng Lin, in its native form. The July 27, 2017 email references ZHP's knowledge that its Valsartan was contaminated with NDMA, in discussing the problems presented by the finding of another nitrosamine impurity in Irbesartan, a similar drug substance manufactured by ZHP with a similar process as used to manufacture Valsartan. The native form of the document is the primary electronic form of the document, including the metadata for the document, which is information embedded in an electronic document. The metadata would have included information about when the document was written, who it was sent and forwarded to and when, and other relevant information. Instead, ZHP only produced a copy of the July 27, 2017 email in PDF form,

without the metadata for the document. This deprived the Plaintiffs of their right to be provided the July 27, 2017 email in its primary electronic form with its metadata, so that the Plaintiffs could fully investigate and understand the email. In addition, despite the email being sent to numerous key personnel at ZHP, it was not produced in the custodial file for the author of the email, Jinsheng Lin, and was only produced in the custodial file of one of the numerous recipients of the email, Min Li. In addition, ZHP created an internal Irbesartan Report addressing ZHP's investigation into the nitrosamine impurity found in Irbesartan referenced in the July 27, 2017 email. ZHP failed to produce all drafts of the Irbesartan Report, as required, and the single draft produced was not produced in its native, primary electronic form with its metadata. This deprived the Plaintiffs of their right to fully understand and investigate the report and ZHP's internal investigation and decision making with regard to nitrosamine impurities in its sartan drug substances, including Valsartan. (SMO 98, at 4-10, 21-26, 32-33, 36-37).

RESPONSE: ZHP objects to this instruction for a host of reasons.

First, it would be improper to instruct the jury that ZHP "failed to fully comply" with "Court Orders to produce relevant documents" or to offer any instruction regarding the non-production of documents because these statements are contrary to the record. ZHP's counsel has certified that ZHP produced all responsive documents in its possession that were ordered produced by the Court.

Specifically, on October 21, 2022, ZHP’s counsel executed and provided plaintiffs with a certification that included, *inter alia*: (1) an attestation that counsel had personally investigated the steps taken to identify the whereabouts of the four categories of documents discussed in SMO 54; (2) an attestation that counsel had confirmed that the searches were conducted in manner consistent with the Rules; (3) an exhibit (Exhibit 1) listing the “Bates numbers of the relevant, non-privileged parts of Ms. Kong’s custodial file” produced to Plaintiffs; (4) an attestation that an electronic version of ZHP02710347 was not found following “appropriate steps, consistent with the Rules, . . . taken to locate an electronic version”; (5) an exhibit (Exhibit 2) listing “the Bates numbers of TC-201729 Documents” located; and (6) an exhibit (Exhibit 3) listing the Bates numbers of the requested batch testing records that were produced. (*See generally* Certification of Richard T. Bernardo, Oct. 21, 2022 (attached to Oct. 21, 2022 Email from R. Bernardo to A. Slater & C. Geddis) (“Bernardo Certification”) (attached collectively as Ex. 1 to the Certification of Jessica Davidson).) In light of this sworn statement regarding compliance with the Court’s document discovery orders, it would be entirely inappropriate to instruct the jury that document discovery was incomplete. This is particularly true given that ZHP and its affiliates have produced almost 400,000 documents totaling more than 3.5 million pages, which were collected from more than 90 custodians using more than 400 search terms identified by Plaintiffs. (*Id.*

at 14 n.7.) This includes nearly 1,200 documents from Ms. Kong’s file. (Ex. 1 to Bernardo Certification.)

Second, an instruction that ZHP improperly deprived Plaintiffs of the metadata for the July 27, 2017 email contradicts SMO 54 (ECF [1753](#)). In that Order, the Special Master: (1) noted that Plaintiffs **had not sought** spoliation sanctions with regard to electronic versions of the July 27 email; (2) concluded that ZHP had “provided a credible explanation for the date-created anomaly on the July 27, 2017 email; (3) noted that there was “no testimony . . . that there was a failure to follow litigation hold advice” with respect to the email; and (4) explained there was no “evidence of the loss of any particular data.” (SMO No 54 at 4 (ECF [1753](#))). Indeed, “[g]iven the extensive discovery that has occurred to date and the lack of direct evidence of document destruction or loss,” the Special Master refused to require ZHP “to conduct another search for relevant evidence,” including additional copies of the July 27, 2017 email. (*Id.*)

Third, there is no evidence in the record to support Plaintiffs’ proposed instruction that “[t]he July 27, 2017 email references ZHP’s knowledge that its Valsartan was contaminated with NDMA, in discussing the problems presented by the finding of another nitrosamine impurity in Irbesartan, a similar drug substance manufactured by ZHP with a similar process as used to manufacture Valsartan.” (ECF [2721-1](#), ¶ 5.)

Courts have recognized that an adverse inference instruction must be logically linked to the discovery violation at issue such that it is reasonable to assume that the missing evidence would have contained the information the jury is permitted to infer. *See Emerson v. Wetherill*, No. CIV. 92-4082, 1994 WL 249769, at *3 (E.D. Pa. June 1, 1994) (rejecting adverse inference that a party “committed prior acts of misconduct” as a sanction for the loss of documents because “no reasonable jury could infer that the destroyed documents contained such information”). Plaintiffs lack any support for the assertion that Mr. Chen had knowledge about the July 27, 2017 email such that his deposition testimony would have established that the email indicates that ZHP knew there were nitrosamines in valsartan API as of 2017. As an initial matter, the July 27, 2017 email was not sent to Mr. Chen. (*See generally* ECF [2038-5](#) (ZHP00190573).) In addition, the testimony of those individuals to whom the email *was* sent makes clear that Mr. Chen neither received it, nor was informed of it, prior to its production in this case. (*See, e.g.*, Dep. of Lihong (Linda) Lin 96:5-21, May 4, 2021 (ECF [2663-27](#) at Ex. 1) (Ms. Lin testifying that she did not inform Mr. Chen of Dr. Lin’s July 27 email and that it would be her expectation that “issues such as handling the wastewater would not be reported to Mr. Baohua Chen”); Dep. of Min Li, Ph.D. 598:9-599:19, Apr. 22, 2021 (ECF [2663-12](#)) (Dr. Li testifying that he believes Mr. Chen was not informed of the July 27 email).) Given this evidence, there is absolutely no basis

to presume that Mr. Chen had any information about the meaning of the July 27, 2017 email's substantive content that would have come out at his deposition.

The same is true of Plaintiffs' false assertion that a copy of the "July 27, 2017 email in its primary electronic form with its metadata" could offer insight regarding the *substance and meaning* of the email. The metadata of an email contains technical, electronic information; it says nothing about the meaning of the content of the email or the message it was intended to convey. And metadata certainly could not establish that the email proves that ZHP knew about the presence of nitrosamines in valsartan API as of the date of the email, which is what Plaintiffs want the Court to direct the jury to assume.

PROPOSED FINDING OF FACT 6: The Court has determined that Baohua Chen's deposition testimony and the documents ZHP failed to produce as required would have provided information that would have been adverse to ZHP, and would have favored the Plaintiffs. (SMO 98, at 33-34, 36-39).

RESPONSE: ZHP objects to this instruction. To the extent any instruction regarding ZHP's discovery conduct is appropriate, which ZHP disputes, the instructions should be revised as follows: "The jury may presume that Mr. Chen's deposition testimony would have been favorable to Plaintiffs, but the jury is permitted to consider rebuttal evidence offered by ZHP and determine whether to draw such an adverse inference regarding the content of Mr. Chen's testimony."

PROPOSED FINDING OF FACT 7: The Court has determined that ZHP, at Baohua Chen's direction, covered up and prevented the disclosure of ZHP's actual knowledge of the nitrosamine contamination of ZHP's Valsartan from at least July 27, 2017 until ZHP's customer Novartis discovered the contamination and informed ZHP of its discovery in June, 2018. ZHP then disclosed the contamination. (SMO 98, at 36-39.)

RESPONSE: ZHP objects to this instruction. As noted in detail in Response to Proposed Finding of Fact 5, there is no evidence in the record that Mr. Chen's deposition testimony—or any of the document discovery at issue—would have included information indicating that ZHP, at Mr. Chen's direction, covered up and prevented the disclosure of ZHP's actual knowledge of nitrosamines in ZHP's valsartan API as of July 27, 2017. Thus, there is no basis to assert that the allegedly missing evidence would have established that the July 27, 2017 email informed Mr. Chen, or anyone else at ZHP, that valsartan API contained nitrosamines. Nor is there any logical basis to assert that ZHP or Mr. Chen actively concealed that information.

PROPOSED FINDING OF FACT 9: The Court has determined that ZHP violated its Court ordered legal obligations to produce Baohua Chen for his deposition and produce documents as required because ZHP and Mr. Chen knew of the nitrosamine contamination of ZHP's Valsartan at least as of July 27, 2017, and

at Mr. Chen's direction covered up and prevented disclosure of the nitrosamine contamination until ZHP's customer Novartis discovered the contamination and informed ZHP of its discovery in June, 2018. ZHP then disclosed the contamination. (SMO 98, at 36-39.)

RESPONSE: ZHP objects to this instruction for similar reasons set forth with respect to Proposed Findings of Fact 4, 5 and 8. As noted above, there is no evidence in the record that Mr. Chen's deposition testimony—or any document discovery at issue—would include information indicating that ZHP or Mr. Chen had knowledge of the nitrosamines in ZHP's valsartan API as of July 27, 2017, much less that ZHP or Mr. Chen covered up that information. Nor is there any evidence that ZHP affirmatively precluded Mr. Chen from testifying—or prevented the production of documents—for the purpose of withholding relevant information regarding the July 27, 2017 email from Plaintiffs. To the contrary, any fair instruction regarding Mr. Chen's inability to testify must reference the fact that ZHP affirmatively sought permission from the Chinese government to allow Mr. Chen to travel outside mainland China to provide a deposition and that permission was denied.

Dated: May 31, 2024

Respectfully submitted,

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CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on May 31, 2024, I electronically filed the foregoing with the Clerk of the Court by using the CM/ECF system which will send a notice of electronic filing to all CM/ECF participants in this matter.

/s/ Jessica Davidson
Jessica Davidson